



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-2735]

Scientific Inquiry Into How Mobile Health and Social Data Sources May Inform Medical Product Safety and Efficacy; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA), in collaboration with the University of Maryland's Center of Excellence in Regulatory Science and Innovation (M-CERSI) is announcing a public workshop entitled "Scientific Inquiry Into How Mobile Health and Social Data Sources May Inform Medical Product Safety and Efficacy." The purpose of the public workshop is to discuss important scientific questions about using two of the most ubiquitous and fastest growing data sources, mobile health data and social computing data, focusing especially on the implications for product safety.

DATES: The public workshop will be held on September 11, 2015, from 12:30 p.m. to 5:30 p.m.

ADDRESSES: The public workshop will be held at the Adele H. Stamp Student Union, University of Maryland, 1021A Adele H. Stamp Student Union, College Park, MD. For additional travel and hotel information, please refer to: <http://go.umd.edu/mobilesocialanalytics>.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Regarding this notice: Leslie D. Wheelock, Food and Drug Administration, Office of the Commissioner, 10903 New Hampshire Ave., Bldg. 1, rm. 4345, Silver Spring, MD 20993, 301-796-8450, FAX: 301-847-8106; email: [leslie.wheelock@fda.hhs.gov](mailto:leslie.wheelock@fda.hhs.gov).

Regarding registration: Ann Anonsen, University of Maryland, Fischell Dept. of Bioengineering, 2207 Jeong H. Kim Bldg., College Park, MD 20742, 301-405-0285, FAX: 301-405-9953, email: [aanonsen@umd.edu](mailto:aanonsen@umd.edu).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Mobile health and social computing data sources create unique and hitherto unavailable opportunities, but there are important questions that need to be answered. This workshop will bring together thought leaders from industry, academia, and the regulatory communities to reflect on the opportunities and challenges that these new data sources create.

##### II. Attendance and Registration

There is a registration fee to attend this public workshop. The registration fee is charged to help defray the costs for facilities, materials, and food. Seats are limited, and registration will be on a first-come, first-served basis. The costs of registration for the different categories of attendees are as follows:

Category	Cost
Industry Representatives	\$50

Charitable Nonprofit/Academic	\$50
Government/Students	\$0

Persons interested in attending this public workshop must register online at

<http://go.umd.edu/mobilesocialanalytics> by September 1, 2015. To register, please refer to:

<http://www.rhsmith.umd.edu/centers-excellence/center-health-information-decision-systems/events/m-cersi-workshop>. Early registration is recommended because space is limited.

Those without Internet access should contact Ann Anonsen to register (see FOR FURTHER INFORMATION CONTACT regarding registration).

Attendees are responsible for their own hotel accommodations. If you need special accommodations due to a disability, please contact Ann Anonsen, at 301-405-0285 or email: [aanonsen@umd.edu](mailto:aanonsen@umd.edu).

### III. Comments

Regardless of attendance at the public workshop, interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). The deadline for submitting comments related to this public workshop is August 28, 2015. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: August 10, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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